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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,717	12/21/1999	HUGH L. NARCISO JR.	353532000710	5304

7590 03/14/2002

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EXAMINER	
DROESCH, KRISTEN L	

ART UNIT	PAPER NUMBER
3762	18

DATE MAILED: 03/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/469,717	NARCISO, HUGH L.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 11/21/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/469717 is acceptable and a CPA has been established. An action on the CPA follows.

Information Disclosure Statement

2. Some of the references listed in the PTO-1449 form were not considered since they were unavailable to the examiner. The examiner requests copies of these references.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 51, and 62-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the limitation "the portion of the tubular member" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 48 recites the limitation "the longitudinal centerline" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 51 recites the limitation "said biocompatible material" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 60 recites the limitation "said graft vessel" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 62-67 recite the limitation "the fastener of claim 61" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 46-59, and 61-67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The anastomosis device comprising a graft vessel where the graft vessel is described a thoracic artery or saphenous vein in Col. 5, line 7 of the specification is directed to non-statutory subject matter because the claims positively recite part of the human body. The examiner suggests replacing the existing phrases to language such as -- where the tubular member is adapted to be connected to a graft vessel--.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 46, 49-55, 58-62, and 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Slepian (5,634,946). Slepian shows an anastomosis device (Col. 12, lines 9-12), comprising a tubular member made of a deformable material, which is transformable upon application of energy between a non-fluent state and a fluent state in which the tubular member is radially expandable (Col. 10, lines 46-60).

With respect to claims 49-51, and 62, Slepian shows that the tubular member is formed of a biocompatible, bioerodable polymeric material (Col. 7, lines 32-44, Col. 8, lines 4-15).

Regarding claim 52, Slepian shows the polymer is either a homopolymer or a copolymer (Col. 7, lines 46-49).

With respect o claim 53, Slepian shows the polymeric material is polycaprolactone (Col. 8, lines 16-46).

Regarding claims 54-55, Slepian shows the tubular member has an adhesive surface (Col. 12, lines 9-12, Col. 12, lines 52-56, Col. 14, lines 40-46)

With respect to claims 58-59, 64, and 65, Slepian shows the tubular member is impregnated with anti-platelet, anti-thrombus, anti-inflammatory, and anti-proliferative compounds (Col. 9, lines 25-43).

Regarding claims 60-61, Slepian shows the tubular member is sized and dimensioned for receiving an end portion of a graft vessel, and that the material can be disposed upon an end margin of a free end of a graft vessel (Col. 10, lines 46-49). Although not specifically stated, it is inherent that the tubular member is radially expanded.

With respect to claims 66-67, Slepian shows the material can be applied to an inner wall of a graft vessel (Col. 5, lines 28-34). Although not specifically stated, it is inherent that the material can be applied to an outer wall of a graft vessel.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash et al (6,056,762). Slepian is as explained before. Slepian teaches that the initial pre-deployment design and size of the polymer sleeve will be dictated by the specific application based upon the final physical, psychological, and pharmacological properties desired (Col. 12, lines 28-32). Although Slepian does not teach that the tubular member is pre-shaped to have at least a first bend along the length of the member or a portion of the tubular member extends at an angle of between 30° and 90° relative to a longitudinal centerline, attention is directed to Nash et al. which shows an anastomosis system comprising a tubular member (22) with a first bend along the length of the member (Fig. 3). Nash et al. shows that a portion of the tubular member extends at an angle between 30° and 90° relative to a centerline (Fig. 3, Col. 6, lines 44-47). Nash et al teaches that the angled configuration facilitates insertion into the target vessel (Col. 6, lines 46-50). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the tubular member of Slepian with a first bend or a portion of the

tubular member extending at and angle between 30° and 90° relative to a centerline as Nash et al. teaches in order to facilitate insertion into a target vessel.

11. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712). Slepian is as explained before. Although Slepian does not teach of including in the tubular member a chromophore or dye, attention is directed to Pathak which teaches of forming polymeric materials that include a chromophore such as a dye or pigment (Col. 2, lines 54-59). Pathak teaches that the chromophore serves to absorb light produced by a light source and convert it to thermal energy that acts to heat the polymer. It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in the tubular member of Slepian a chromophore in the form of a dye, as taught by Pathak in order for the tubular member to be transformable by the application of light energy.

12. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Slepian is as explained before. Although Slepian does not teach that the material is selected from a group consisting of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes, attention is directed to Hubbell which teaches tissue contacting materials formed from of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes (Col. 5, lines 15-23, and Col. 27, lines 53-55). Hubbell teaches that the acrylates permit rapid polymerization and gelation and can be polymerized by several initiating systems. Hubbell teaches that PEG is hydrophilic and water soluble and has excellent biocompatibility. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to use this group of materials for the device of Slepian since Hubbell teaches that this group of materials are rapidly transformable upon the application

of energy between a non-fluent state and a fluent state, are water soluble, and have excellent biocompatibility.

Conclusion

13. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbell (5,573,934) also teaches of the use of PEG base hydrogels, acrylates, and acrylated urethanes.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld
February 26, 2002

KENNEDY SCHAETZLE
PRIMARY EXAMINER
2-27-02